



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73, 172, 173, 176, 177, 178, 184, and 189

[Docket No. FDA-2012-N-0010]

Food and Color Additives; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations regarding food and color additives to correct minor errors (such as misspelled chemical names) and to update office names and addresses. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: We are making technical amendments to our regulations under 21 CFR parts 73, 172, 173, 176, 177, 178, 184, and 189. In brief, these amendments are as follows:

- Correct misspelled chemical names in §§ 73.3129, 176.180, and 177.1210. For example, we are revising § 73.3129 to replace “Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9, 10-dihydro-9,10-dioxoanthracene-2-sulphonate” with “Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate”;
- Correct a table entry in § 177.1500 regarding the melting point of certain nylon 12T resins; and
- Amend §§ 172.712, 172.723, 172.809, 172.831, 172.833, 172.886, 173.25, 173.45, 173.325, 173.368, 177.1350, 177.1360, 177.1637, 177.2440, 177.2600, 178.1010, 178.3297, 184.1012, 184.1024, 184.1034, 184.1063, 184.1259, 184.1316, 184.1415, 184.1583, 184.1595, 184.1866, 184.1914, 184.1985, 189.110, and 189.180 to remove archaic or obsolete office names and replace them with the current Office name “Office of Food Additive Safety.” Where appropriate, we also are updating the street address to reflect our present location at 5100 Paint Branch Parkway, College Park, MD 20740, and contact information to reflect our new telephone number, 240-402-1200.

The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required. Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments are merely correcting

nonsubstantive errors. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 173

Food additives.

21 CFR Parts 176, 177, and 178

Food additives, Food packaging.

21 CFR Part 184

Food additives, Substances generally recognized as safe.

21 CFR Part 189

Food additives, Food packaging, Substances prohibited from use in human food.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 73, 172, 173, 176, 177, 178, 184, and 189 are amended as follows:

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Amend § 73.3129 as follows:

a. Revise the section heading to read as set forth below.

b. In paragraph (a), remove “disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate” and in its place add “disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate”.

§ 73.3129 Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate.

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PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

3. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.712 [Amended]

4. In § 172.712, in paragraph (b), remove “the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740 ” and in its place add “the Office of Food Additive Safety (HFS-200) , Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.723 [Amended]

5. In § 172.723, in paragraph (b)(1), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety

(HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.809 [Amended]

6. In § 172.809, in paragraph (b), remove “Division of Petition Control (HFS-215) , Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200) , Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.831 [Amended]

7. In § 172.831, in paragraph (b), remove “Division of Product Policy (HFS-206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.833 [Amended]

8. In § 172.833, in paragraph (b)(2), remove “Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.886 [Amended]

9. In § 172.886, in paragraph (c)(2)(iii), remove “Office of Premarket Approval (HFS-200) , Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint

Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200) , Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR
HUMAN CONSUMPTION

10. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

§ 173.25 [Amended]

11. In § 173.25, in paragraph (b)(2)(ii)(B), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 173.45 [Amended]

12. In § 173.45, in paragraph (a), remove “Division of Product Policy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 173.325 [Amended]

13. In § 173.325, in paragraph (h), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety

(HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 173.368 [Amended]

14. In § 173.368, in paragraph (c), remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 176--INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

15. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

§ 176.180 [Amended]

16. In § 176.180, in the table in paragraph (b)(2), in the first column, remove “Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt” and in its place add “Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt”; and remove “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt” and in its place add “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt”.

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS

17. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1210 [Amended]

18. In § 177.1210, in table 1 in paragraph (b)(5), in the first column, remove “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt” and in its place add

“Naphthalene sulfonic acid-formaldehyde condensate, sodium salt”; and remove “Sodium salt of trisopropyl naphthalenesulfonic acid” and in its place add “Sodium salt of trisopropyl naphthalenesulfonic acid”.

§ 177.1350 [Amended]

19. In § 177.1350, in paragraph (b)(2), remove “Division of Petition Control (HFS-215) Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 177.1360 [Amended]

20. In § 177.1360, in paragraph (d), remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200)), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 177.1500 [Amended]

21. In § 177.1500, in table 1 in paragraph (b), in the third column of the entry for “11. Nylon 12T resins for use in contact with all types of food except those containing more than 8 percent alcohol,” remove “290-310” and in its place add “N/A”.

§ 177.1637 [Amended]

22. In § 177.1637, in paragraph (b)(2), remove “Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety

(HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 177.2440 [Amended]

23. In § 177.2440, in paragraph (a)(3), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, 1110 Vermont Ave. NW., suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 177.2600 [Amended]

24. In §177.2600, in paragraph (c)(4)(i), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND
SANITIZERS

25. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.1010 [Amended]

26. In §178.1010, in paragraph (c)(40), remove “Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety

(HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 178.3297 [Amended]

27. Amend § 178.3297 as follows:

a. In paragraph (c), remove “Center for Food Safety and Applied Nutrition, (HFS-200) Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740,” and in its place add “Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

b. In paragraph (e), in the entry for “High-purity furnace black,” remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

28. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 184.1012 [Amended]

29. In § 184.1012, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC” and in its place add “Office Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1024 [Amended]

30. In § 184.1024, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1034 [Amended]

31. In § 184.1034, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1063 [Amended]

32. In §184.1063, in paragraph (b)(8), remove “Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1259 [Amended]

33. In §184.1259, in paragraph (b)(8), remove “Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive

Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1316 [Amended]

34. In § 184.1316, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1415 [Amended]

35. In § 184.1415, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1583 [Amended]

36. In § 184.1583, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1595 [Amended]

37. In § 184.1595, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its

place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1866 [Amended]

38. In § 184.1866, in paragraph (b), remove “Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1914 [Amended]

39. In § 184.1914, in paragraph (b), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 184.1985 [Amended]

40. In § 184.1985, in paragraph (b), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 189--SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

41. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371, 381.

§ 189.110 [Amended]

42. In §189.110, in paragraph (c), remove “Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 189.180 [Amended]

43. In § 189.180, in paragraph (c), remove “Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

Dated: February 1, 2013.

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[FR Doc. 2013-04701 Filed 03/06/2013 at 8:45 am; Publication Date: 03/07/2013]